

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1 (currently amended). A retractor for manipulating an object, comprising:

a body having proximal and distal ends;

a retraction device having:

a head connected to said distal end of said body;

an actuator movably disposed in said head; and

first and second substantially rigid needles independent of one another
and each independently movably connected to said actuator and having an
arcuate shape; and

an actuation device connected to said proximal end of said body and operatively
connected to said actuator through said body, said actuation device, upon actuation
thereof, moving said actuator to selectively extend said needles out of said head and
withdraw said needles into said head.

2 (original). The retractor according to claim 1, wherein:

said body has a longitudinal extent defining a longitudinal direction; and

said needles extend out of said head in a direction substantially orthogonal to
said longitudinal direction.

3 (original). The retractor according to claim 1, wherein said head is connected
removably to said distal end of said body.

4 (original). The retractor according to claim 1, wherein said head is integrally formed
with said body.

5 (original). The retractor according to claim 1, wherein said head defines openings for respective ones of said needles.

6 (original). The retractor according to claim 5, wherein said openings are disposed to permit movement of said needles therethrough without substantial deformation of said needles.

7 (original). The retractor according to claim 5, wherein said openings are disposed to permit movement of said needles therethrough substantially without friction.

8 (original). The retractor according to claim 5, wherein said openings are disposed on opposing sides of said head and said needles are disposed on opposing sides of said actuator in substantial alignment with said openings.

9 (original). The retractor according to claim 8, wherein at least one surface of said openings guide said needles in a direction substantially orthogonal to a movement direction of said actuator.

10 (original). The retractor according to claim 1, wherein said actuation device is connected removably to said proximal end of said body.

11 (original). The retractor according to claim 1, wherein said actuator is movably disposed in said body.

12 (original). The retractor according to claim 1, wherein said arcuate shape of said needles is no greater than a circle.

13 (original). The retractor according to claim 1, wherein said arcuate shape of said needles is no greater than a semi-circle.

14 (original). The retractor according to claim 1, wherein said needles are two needles.

15 (original). The retractor according to claim 1, wherein said needles are of a material selected from at least one of the group consisting of a steel, a non-pseudo-elastic metal, a ceramic, and a polymer.

16 (original). The retractor according to claim 1, wherein said needles are connected pivotably to said actuator.

17 (original). The retractor according to claim 1, wherein:

said body has a coil winding and an outer jacket surrounding said coil winding;
and

said actuator is movably disposed in said coil winding and said head.

18 (original). The retractor according to claim 1, wherein said retraction device grasps the object upon extension of said needles out of said head and releases the object upon withdrawal of said needles into said head.

19 (original). The retractor according to claim 1, wherein:

said actuation device has a rod; and

said rod passes through said body and is connected to said actuator for moving said actuator.

20 (original). The retractor according to claim 19, wherein said rod is integrally formed with said actuator.

21 (original). The retractor according to claim 19, wherein said rod is removably connected to said actuator.

22 (original). The retractor according to claim 1, further comprising a proximal stop disposed in said body and limiting a retraction range of said needles.

23 (original). The retractor according to claim 1, wherein said actuation device has a locking device selectively retaining said needles in a given position.

24 (original). The retractor according to claim 23, wherein said locking device selectively retains said needles in an extended position.

25 (original). The retractor according to claim 1, wherein said actuation device has an overstroke preventor limiting an extension distance of said needles out of said head.

26 (original). The retractor according to claim 1, wherein said actuation device is a one-handed actuation device.

27 (original). The retractor according to claim 5, wherein said head has cam surfaces guiding said needles through said openings.

28. (original) The retractor according to claim 1, wherein said head has an anchoring spike retaining said head at a user-selected placement position.

29 (currently amended). In combination with a flexible endoscope having at least one working channel, a tissue retractor for manipulating tissue inside a patient, comprising:

- a body having proximal and distal ends;

- a retraction device having:

- a head connected to said distal end of said body;

- an actuator movably disposed in said head; and

- first and second substantially rigid needles independent of one another and each independently movably connected to said actuator and having an arcuate shape; and

- an actuation device connected to said proximal end of said body and operatively connected to said actuator through said body, said actuation device, upon actuation thereof, moving said actuator to selectively extend said needles out of said head and withdraw said needles into said head;

wherein said body and said retraction device are sized to fit within the working channel of the endoscope.

30 (original). The retractor according to claim 29, wherein said needles are sized to selectively grasp alimentary tract tissue.

31 (original). The retractor according to claim 29, wherein said needles are sized to extend into mucosa without extending into muscularis.

32 (original). The retractor according to claim 29, wherein said needles are sized to extend through mucosa and into muscularis.

33 (original). The retractor according to claim 29, wherein said needles are sized to extend into mucosa and muscularis without extending into serosa.

34 (original). The retractor according to claim 29, wherein said needles are sized to selectively extend through different layers in the gastric wall.

35 (original). The retractor according to claim 29, wherein:

said head defines openings on opposing sides thereof;

said needles are disposed on opposing sides of said actuator in substantial alignment with said openings; and

at least one surface of said openings guide said needles in a direction substantially orthogonal to a movement direction of said actuator.

36 (original). The retractor according to claim 29, wherein:

said body has a longitudinal extent defining a longitudinal direction; and

said needles extend out of said head in a direction substantially orthogonal to said longitudinal direction.

37 (original). The retractor according to claim 29, wherein said head is connected removably to said distal end of said body.

38 (original). The retractor according to claim 29, wherein said head is integrally formed with said body.

39 (original). The retractor according to claim 35, wherein said openings are disposed to permit movement of said needles therethrough without substantial deformation of said needles.

40 (original). The retractor according to claim 35, wherein said openings are disposed to permit movement of said needles therethrough substantially without friction.

41 (original). The retractor according to claim 29, wherein said actuation device is connected removably to said proximal end of said body.

42 (original). The retractor according to claim 29, wherein said needles are two needles.

43 (original). The retractor according to claim 29, wherein said needles are of a material selected from at least one of the group consisting of a steel, a non-pseudo-elastic metal, a ceramic, and a polymer.

44 (original). The retractor according to claim 29, wherein said needles are connected pivotably to said actuator.

45 (original). The retractor according to claim 29, further comprising a proximal stop disposed in said body and limiting a retraction range of said needles.

46 (original). The retractor according to claim 29, wherein said actuation device has a locking device selectively retaining said needles in a given position.

47 (original). The retractor according to claim 46, wherein said locking device selectively retains said needles in an extended position.

48 (original). The retractor according to claim 29, wherein said actuation device has an overstroke preventor limiting an extension distance of said needles out of said head.

49 (currently amended). A tissue retractor, comprising:

- a body having proximal and distal ends;

- a retraction device having:

 - a head connected to said distal end of said body and defining two opposing openings;

 - an actuator movably disposed in said head; and

 - two substantially rigid needles independent of one another and each independently pivotably connected to said actuator for traveling through a respective one of said openings, said needles having an arcuate shape; and

- a one-handed actuation device connected to said proximal end of said body and operatively connected to said actuator through said body, said actuation device, upon actuation thereof, moving said actuator to selectively extend said needles out of said head and withdraw said needles into said head.

50 (withdrawn). A method for retracting tissue, which comprises:

- positioning a flexible endoscope having at least one working channel adjacent a location of tissue to be retracted;

- passing the tissue retractor according to claim 1 through the working channel of the endoscope;

 - positioning the head of the retractor at a desired retraction location on the tissue;

 - actuating the actuation device to extend the needles into the tissue at the desired retraction location; and

 - retracting the tissue with the retractor.

51 (withdrawn). The method according to claim 50, which further comprises actuating the actuation device to retract the needles back into the head to release the tissue.

52 (withdrawn). A method for retracting tissue, which comprises:

- positioning the endoscope according to claim 29 adjacent a location of tissue to be retracted;

- passing the tissue retractor through the working channel of the endoscope;

positioning the head of the retractor at a desired retraction location on the tissue;
actuating the actuation device to extend the needles into the tissue at the
desired retraction location; and
retracting the tissue with the retractor.

53 (withdrawn). The method according to claim 52, which further comprises actuating the actuation device to retract the needles back into the head to release the tissue.

54 (withdrawn). A method for retracting tissue for the treatment of Gastroesophageal Reflux Disease, which comprises:

positioning a flexible endoscope having at least one working channel adjacent a
desired retraction location of the wall of the stomach;

passing the tissue retractor according to claim 1 through the working channel of
the endoscope;

positioning the head of the retractor on the desired retraction location of the
stomach wall;

actuating the actuation device to extend the needles into the stomach wall at the
desired retraction location; and

retracting the stomach wall with the retractor.

55 (withdrawn). The method according to claim 54, which further comprises shaping a
curvature of the needles to limit penetration of the stomach wall to a depth no greater
than the muscularis.

56 (withdrawn). The method according to claim 54, which further comprises:

providing a clip implantation and plication instrument having a proximal actuating
handle and a distal end effector with jaws, the jaws containing male and female parts of
a plication fastener;

positioning the end effector adjacent the retracted stomach wall;

operating the proximal actuating handle to cause the jaws of the end effector to
open;

pulling the retracted stomach wall between the opened jaws of the end effector;

operating the actuation handle to cause the jaws to close about the retracted stomach wall while holding a substantially central point of the stomach wall between the jaws with the retractor and form a tissue plication with the jaws as the male and female parts of the fastener are brought together with the plication clamped therebetween;

when the jaws are closed about the plication, deploying the fastener to pierce the plication with the male part of the fastener through the serosal layers of the plication forming a serosa-to-serosa contact on the inside surfaces of the plication;

determining a satisfactory location and size of the plication and relative position of the fastener parts with the endoscope and:

if a satisfactory implantation is determined, operating the proximal actuation handle to lock the male and female parts of the fastener and to release the locked fastener from the jaws; and

if a satisfactory implantation is not determined, re-opening and re-orienting the jaws to form another plication until a satisfactory implantation is determined and, then, operating the proximal actuation handle to lock the male and female parts of the fastener and release the locked fastener from the jaws; opening the jaws; and

withdrawing the clip implantation and plication instrument and the endoscope through the esophagus and out of the patient.

57 (withdrawn). The method according to claim 56, which further comprises:

approaching the retracted stomach wall with the jaws in a direction substantially parallel to the esophagus; and

forming the plication substantially parallel to the esophagus.

58 (withdrawn). A method for retracting tissue for the treatment of Gastroesophageal Reflux Disease, which comprises:

positioning the endoscope according to claim 29 adjacent a desired retraction location of the stomach wall of the stomach;

passing the tissue retractor through the working channel of the endoscope;

positioning the head of the retractor on the desired retraction location of the stomach wall;

actuating the actuation device to extend the needles into the stomach wall at the desired retraction location; and
retracting the stomach wall with the retractor.

59 (withdrawn). The method according to claim 58, which further comprises shaping a curvature of the needles to limit penetration of the stomach wall to a depth no greater than the muscularis.

60 (withdrawn). The method according to claim 58, which further comprises:

providing a clip implantation and plication instrument having a proximal actuating handle and a distal end effector with jaws, the jaws containing male and female parts of a plication fastener;

positioning the end effector adjacent the retracted stomach wall;

operating the proximal actuating handle to cause the jaws of the end effector to open;

pulling the retracted stomach wall between the opened jaws of the end effector;

operating the actuation handle to cause the jaws to close about the retracted stomach wall while holding a substantially central point of the stomach wall between the jaws with the retractor and form a tissue plication with the jaws as the male and female parts of the fastener are brought together with the plication clamped therebetween;

when the jaws are closed about the plication, deploying the fastener to pierce the plication with the male part of the fastener through the serosal layers of the plication forming a serosa-to-serosa contact on the inside surfaces of the plication;

determining a satisfactory location and size of the plication and relative position of the fastener parts with the endoscope and:

if a satisfactory implantation is determined, operating the proximal actuation handle to lock the male and female parts of the fastener and to release the locked fastener from the jaws; and

if a satisfactory implantation is not determined, re-opening and re-orienting the jaws to form another plication until a satisfactory implantation is determined and, then, operating the proximal actuation handle to lock the male and female parts of the fastener and release the locked fastener from the jaws;

opening the jaws; and
withdrawing the clip implantation and plication instrument and the endoscope through the esophagus and out of the patient.

61 (withdrawn). The method according to claim 60, which further comprises:
approaching the retracted stomach wall with the jaws in a direction substantially parallel to the esophagus; and
forming the plication substantially parallel to the esophagus.

62 (withdrawn). The method according to claim 50, which further comprises:
providing the retractor with a removable handle; and
removing the handle after the needles are extended into the tissue.

63 (withdrawn). The method according to claim 62, which further comprises guiding a second endoscope over the body of the retractor towards the head of the retractor.

64 (withdrawn). The method according to claim 52, which further comprises:
providing the retractor with a removable handle;
removing the handle after the needles are extended into the tissue; and
guiding a second endoscope over the body of the retractor towards the head of the retractor.

65 (withdrawn). A method for grasping an object, which comprises:
positioning the head of the retractor according to claim 1 at a desired location on the object;
actuating the actuation device to extend the needles into the object at the desired location to grasp the object with the retractor.

66 (original). The retractor according to claim 1, wherein said body is one of the group consisting of a flexible body and a rigid body.

67 (original). The retractor according to claim 29, wherein said body is one of the group consisting of a flexible body and a rigid body.

68 (original). The retractor according to claim 1, wherein said actuation device, upon actuation thereof, moving said actuator to selectively extend said needles out of said head into tissue of a patient and withdraw said needles from the tissue into said head.

69 (original). The retractor according to claim 1, wherein said needles are sized to control penetration depth through tissue.